510(K) SUMMARY

SEP - 5 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K061442

Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888

Fax: +86 755 2658 2680

- **Contact Person:**

Li Dongling
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

May 12, 2006

Name of the device:

- **Trade/Proprietary Name:** PM-50 Pulse Oximeter
- **Common Name:** Pulse Oximeter
- **Classification**

21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 870.2710	Ear Oximeter, Pulse	Class II

Legally Marketed Predicate Device:

0026

K052693 PM-50 Pulse Oximeter

Description:

The PM-50 is a flexible, portable, battery powered Pulse Oximeter. The PM-50 Pulse Oximeter acquires the physiological signals – oxygen saturation (SpO_2) and pulse rate (PR). The signals are converted into digital data and processed, and the SpO2 and pulse rate values are calculated and displayed on LCD screen.

PM-50 uses a two-wavelength pulsatile system - red and infrared light – to obtain SpO_2 based on the different light absorption of oxygenated and reduced hemoglobin. The light source in the finger sensor emits red and infrared light, which are partially absorbed and modulated by the arterial blood pulsation at the sensor site. The photodetector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The electronic signals are sent to the oximeter and processed by the oximeter's circuitry. Thereafter, the SpO_2 and pulse rate are obtained and indicated on the LCD screen.

Statement of intended Use:

The PM-50 Pulse Oximeter is a non-invasive, spot-check, oxygen saturation and pulse rate monitor. It operates only on battery power using existing PM-50 disposable and reusable sensors labeled for patients ranging from neonates to adults.

Comparison of Technological Characteristics:

The PM-50 Pulse Oximeter employs the same functional technology as the predicate device.

Testing:

The device modification involved the addition of SpO_2 probes for the PM-50 Pulse Oximeter. The purpose of adding these added probes is a business decision. The subject new probes are selectable by customers; we will not discontinue marketing the previously cleared probes.

Laboratory testing and clinical study was conducted to validate and verify that the PM-50 Pulse Oximeter met all design specifications and was substantially equivalent to predicate device.

0027

The following quality assurance measures were applied to the development of the

device:

- Risk Analysis
- Environmental Testing
- Function and Performance Testing
- Clinical Study

Conclusion:

The conclusions drawn from clinical and laboratory testing of the PM-50 Pulse Oximeter demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the PM-50 Pulse Oximeter numbered K#052693.

0028

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Shenzhen Mindray Bio-Medical Electronics Company, Limited
C/O Ms. Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K061442
Trade/Device Name: PM-50 Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: August 8, 2006
Received: August 9, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #E

510(k) Number (if known): _____

Device Name: PM-50 Pulse Oximeter

Indications For Use:

The PM-50 Pulse Oximeter is a non-invasive, spot-check, oxygen saturation and pulse rate monitor. It operates only on battery power using existing PM-50 disposable and reusable sensors labeled for patients ranging from neonates to adults.

Prescription Use __X___ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ction Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...(k) Number: K061442